UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,

Plaintiff,

Case No. _____

v.

169 / 50kg drums, more or less, of an article of drug for human use, labeled in part:

(drum)

"*** PVP IODINE (USP) *** POVIDONE IODINE (USP) *** FOR MANUFACTURING PROCESSING OR REPACKING *** NET WT.: 50.00 KG ***"

and

all other articles of drug, including finished and in-process products, and drug components, including active and inactive ingredients, of any lot number, size, or type of container, whether labeled or unlabeled, that are determined to consist in whole or in part of components that have originated from outside the State of Wisconsin, which articles were manufactured by, or are used in the manufacture of finished dosage form drugs by, H & P Industries, Inc., and that are located anywhere on the premises of H & P Industries, Inc., 700 W. North Shore Drive, Hartland, Wisconsin,

Defendants.

COMPLAINT FOR CIVIL FORFEITURE IN REM

Plaintiff, the United States of America, by James L. Santelle, United States Attorney for the Eastern District of Wisconsin, respectfully brings this complaint and alleges as follows in accordance with Supplemental Rule G(2) of the Federal Rules of Civil Procedure:

NATURE OF THE ACTION

1. This complaint is filed by the United States of America, and requests seizure and condemnation of articles of drug, as described in the caption, for violations of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 et seq.

2. The articles of drug, as described in the caption, are in the possession of H & P Industries, Inc., ("H & P" or "the firm"), 700 W. North Shore Drive, Hartland, Wisconsin, or elsewhere within the jurisdiction of this Court, which articles consist in whole or in part of components received from outside the State of Wisconsin.

JURISDICTION AND VENUE

3. Plaintiff brings this action in rem in its own right to condemn and forfeit the defendant property. This Court has jurisdiction over an action commenced by the United States under 28 U.S.C. § 1345 and 21 U.S.C. § 334, which provide the Court with jurisdiction over seizures brought under the Act.

4. This Court has in rem jurisdiction over the articles because they are located in the Eastern District of Wisconsin. Upon filing of this complaint, the plaintiff requests that the Court issue an arrest in rem pursuant to Supplemental Rule G(3)(b), which the plaintiff will execute upon the property pursuant to Supplemental Rule G(3).

5. Venue is proper in this District pursuant to 28 U.S.C. § 1395(b) and 21 U.S.C. § 334(a)(1) because the defendant property is located at H & P Industries, Inc., 700 W. North Shore Drive, Hartland, Wisconsin.

BASIS FOR FORFEITURE

6. The article listed in the caption are drugs, which may not be introduced or delivered for introduction into interstate commerce pursuant to the Act, 21 U.S.C. § 351(a)(2)(B), in that the methods used in, and the facilities and controls used for, their manufacture, processing, packing, and holding do not conform to and are not operated and administered in conformity with current good manufacturing practice (GMP) requirements for drugs, Title 21, Code of Federal Regulations (21

CFR), Parts 210-211. Thus, there is no assurance that the drugs meet the safety requirements of the Act and have the identity and strength, and meet the quality and purity characteristics, which they purport and are represented to possess.

7. By reason of the foregoing, the articles are held illegally within the jurisdiction of this Court and are liable to seizure and condemnation pursuant to 21 U.S.C. § 334.

FACTS

8. On August 4, 2010, the Food and Drug Administration (FDA) conducted a regulatory meeting with H & P identifying numerous significant GMP violations found during an April 19 - May 18, 2010 inspection. FDA discussed fully each violation with the firm's management and requested that the violations be corrected. FDA stated that failure to correct the violations may result in regulatory action, including seizure and/or injunction. Between August 27 and December 4, 2010, the firm sent eight letters to FDA stating that appropriate actions had been taken to correct the deficiencies.

9. Subsequent FDA inspections conducted on November 29 to January 7, 2011, and on March 21-28, 2011, revealed continuing significant GMP violations including, but not limited to, the following:

- Failure to establish an adequate quality control unit with the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling and drug products [21 CFR § 211.22(a)];
- Failure to establish an expiration date determined by appropriate stability testing as described in 21 CFR 211.166 for drug products to assure that they meet applicable standards of identity, strength, quality and purity at the time of use [21 CFR § 211.137(a)];

- Failure to conduct at least one specific identity test and establish the reliability of a supplier's report of analysis through appropriate validation of the supplier's test results at appropriate intervals [21 CFR § 211.84(d)(2)];
- Failure to conduct thorough investigations of any unexplained discrepancies and failures of batches to meet any of their specifications and failure to extend such investigations to other batches of the same drug product or other drug products that may have been associated with the specific failure or discrepancy [21 CFR § 211.192];
- Failure to provide exhaust systems or other adequate systems to control contaminants during production [21 CFR § 211.46(c)];
- Failure of the quality control unit to approve or reject all procedures and specifications impacting on the identity, strength, quality and purity of the drug product [21 CFR § 211.22(c)]; and
- Failure to clean and maintain equipment at appropriate intervals to prevent contamination that would alter the safety, identity, strength or quality of the drug product [21 CFR § 211.67(a)].

WHEREFORE, the plaintiff respectfully requests that the Court issue a warrant and summons for the arrest and seizure of the defendant property; that all persons having any interest in the articles be cited to appear herein and answer the allegations of the complaint; that this Court decree the condemnation of the articles and grant plaintiff the costs of this proceeding against the claimant of

the articles; that the articles be disposed of as this Court may direct pursuant to the provisions of the Act; and that plaintiff have such other and further relief as the case may require.

Dated this 31st day of March, 2011.

/s/ James L. Santelle
JAMES L. SANTELLE
United States Attorney

SCOTT J. CAMPBELL
Assistant United States Attorney
State Bar # 1017721
SUSAN M. KNEPEL
Assistant United States Attorney
State Bar # 1016482
530 Federal Courthouse
517 E. Wisconsin Avenue
Milwaukee, WI 53202
Tele. No. 414/297-1700
Fax No. 414/297-1738
scott.campbell@usdoj.gov
susan.knepel@usdoj.gov

VERIFICATION

I, BRIAN D. GARTHWAITE, Ph.D., Compliance Officer for the Food and Drug Administration, U.S. Department of Health and Human Services, have read the foregoing Verified Complaint for Forfeiture in rem in this action and state that its contents are true and correct to the best of my knowledge, information, and belief.

I hereby verify and declare under penalty of perjury that the foregoing is true and correct.

Executed on the 31st day of March, 2011.

/s/ Brian D. Garthwaite
BRIAN D. GARTHWAITE, Ph.D.
Compliance Officer
Food and Drug Administration
Department of Health and Human Services